UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 16, 2000

MEMORANDUM

SUBJECT: Malathion: Chem No. 057701: Response to Malathion RED 60-day Public Comments: Maximum Use Patterns for Malathion on Food Crops: DP Barcode D268041.

FROM: William Smith, Chemist
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Health Effects Division (7509C)

THROUGH: F. B. Suhre, Branch Senior Scientist
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TO: Paula Deschamp
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Health Effects Division (7509C)

Cheminova has stated in their response to the Malathion RED that they believe the Agency used incorrect use patterns in assessing dietary risk from uses on food crops. They base this statement on a comparison of Table A2 of the Residue Chemistry Chapter with use patterns tested in residue field trials. Cheminova provided several tables intended to clarify the use patterns that were tested in submitted residue field trials and suggested that the Agency should revise its risk assessments using the information provided in these tables. The purpose of this memorandum is to respond to Cheminova's comments.

CONCLUSION

The registrant's comments do not warrant modification of the RED. The following discussion summarized use-related assumptions that are contained in our tolerance reassessments and dietary

exposure assessments. This information is documented in Table B of the Residue Chemistry Chapter of the RED.

DISCUSSION

The basis of our tolerance reassessments and dietary risk assessments was not Table A2 of the Residue Chemistry Chapter. The basis for these assessments is contained in Table B, Residue Chemistry Science Assessments for Reregistration of Malathion. Column 2 of this table lists the reassessed tolerances, column 3 indicates the adequacy of submitted data, and column 4 lists all references used in making the assessments. The footnotes at the end of the table either explain the use patterns considered or give a reference to another document containing this information. All use pattern assumptions associated with tolerance reassessment and dietary exposure assessment for malathion are found starting with this table.

We are including five additional tables here to summarize the use patterns reflected in the field trials that were considered as the basis for reregistration recommendations. It should be noted that reassessed tolerances are based on the use pattern that would be expected to produce the highest residues of malathion and its oxygen analog on food commodities. Depending on the level of refinement, dietary exposure assessments were based on either a tolerance, field trial data used to set the tolerance, or on monitoring data from USDA or FDA. Tables 1 through 5 summarize the field trial data conducted with EC, ULV, Dust, RTU, and WP formulations, which have been considered in support of tolerance reassessments and reregistration of malathion. These tables are intended to clarify information that is contained in the footnotes to Table B or in references contained therein.

Table 1. Malathion Use Patterns from Field Trials in Support of Tolerances - EC Formulations.

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Alfalfa	43546101	1.25	2 per cutting	14	0
Apple	The RAC tolerance has not been reassessed because additional data are required.				
Apricots	44120001	3.75	4	7	6
Asparagus	44436101	1.25	9	7	1
Avocado	43383501	4.70	2	30	7
Barley	43350402 43414901	1.25	3	7	7
	The reassessed tolerances for barley RACs were based on residue data translated from wheat RACs and are contingent upon label revisions to make the use pattern for barley consistent with wheat.				
Beets, garden	44266401	1.25	5	7	7
	The reassessed tolerances for garden beet RACs were based on residue data translated from turnip RACs and are contingent upon label revisions to make the use pattern for garden beets consistent with turnip.				
Blackberry	44282201	2.0	4	7	1
Boysenberry	44282201	2.0	4	7	1
	The reassessed tolerance for boysenberry was based on residue data translated from blackberry and raspberry and is contingent upon label revisions to make the use pattern for boysenberry consistent with blackberry and raspberry.				
Broccoli	44203901	1.25	5	7	2
Broccoli raab	Uses on broccoli raab and Brussels sprouts are supported by the reassessed crop group tolerance for *Brassica* (cole) leafy vegetables for which adequate residue data on representative crops (broccoli, cabbage and mustard green) are available.				
Brussels sprouts					
Cabbage	44232601	1.25	10	7	7
	Endnote 34 of the Science Chapter's Table B erroneously specifies a maximum of 6 applications per growing season. The reassessed tolerance will support 10 applications per growing season.				
Carrot	44441601	1.25	7	7	7
Cantaloupe	44098401	1.0	6	7	1
Cauliflower	Uses on cauliflower are supported by the reassessed crop group tolerance for *Brassica* (cole) leafy vegetables for which adequate residue data on representative crops (broccoli, cabbage and mustard green) are available.				

Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Celery	Additional data are required for celery to reassess the existing crop group tolerance for leafy vegetables (except *Brassica* vegetables).				
Chayote root	43360401	1.56	2	7	0
	The reassessed tolerance for chayote root was based on residue data translated from potato and is contingent upon label revisions to make the use pattern for chayote root consistent with potato.				
Chayote fruit	43370601	1.88	3	7	1
	The reassessed tolerance for chayote fruit was based on residue data translated from field-grown cucumber and is contingent upon label revisions to make the use pattern for chayote fruit consistent with cucumber.				
Cherries (sweet)	43078702 43108201	3.75	6	7	3
Cherries (tart)					
Chestnut	44478401	5.0	4	7	2
Clover	43545201	1.25	2 per cutting	14	0
Collards	Uses on collards are supported by the reassessed crop group tolerance for *Brassica* (cole) leafy vegetables for which adequate residue data on representative crops (broccoli, cabbage and mustard green) are available.				
Corn, field	43468201 43577401	1.25	3	7	7
Corn, sweet	43361101	1.25	5	5	5
Cotton	43596601	2.5	25	3	0
	Adequate residue data are available to reassess the tolerance for cottonseed provided the registrant complies with the requested label revisions. A tolerance for cotton gin byproducts needs to be proposed.				
Cucumber	43370601	1.88	3	7	1
Dandelion	Additional data are required for the representative member celery, to reassess the existing crop group tolerance for leafy vegetables (except *Brassica* vegetables).				
Dewberry	44282201	2.0	4	7	1
	The reassessed tolerance for dewberry was based on residue data translated from blackberry and is contingent upon label revisions to make the use pattern for dewberry consistent with blackberry.				

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Eggplant	43372901	3.43	5	5	3
		1.56	5	5	1
	The reassessed tolerance for eggplant was based on residue data translated from field-grown tomato and is contingent upon label revisions to make the use pattern for eggplant consistent with tomato.				
Endive (escarole)	Additional data are required for the representative member celery, to reassess the existing crop group tolerance for leafy vegetables (except *Brassica* vegetables).				
Fig	44061201	2.5	3	5	5
Flax	43991401	0.5	1	Not applicable	52
Garlic	43350401 43383301	1.56	5	7	3
	The reassessed tolerance for garlic was based on residue data translated from onion bulb and is contingent upon label revisions to make the use pattern for garlic consistent with onion bulb.				
Grapefruit	43078701	6.25	3	30	7
	The reassessed tolerance for grapefruit was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for grapefruit consistent with orange.				
Grapes	43383401	1.88	2	14	3
Grasses (forage and hay)	43362601	1.25	1	Not applicable	0
Guava	44391501	1.25	13	3	2
Hops	PP#3H5668	0.63	3	7	10
Horseradish	44266401	1.25	5	7	7
	The reassessed tolerance for horseradish was based on residue data translated from turnip root and is contingent upon label revisions to make the use pattern for horseradish consistent with turnip.				
Kale	The uses on kale and kohlrabi are supported by the crop group tolerance for *Brassica* (cole) leafy vegetables for which adequate residue data on representative crops (broccoli, cabbage and mustard green) are available.				
Kohlrabi					
Kumquat	43078701	6.25	3	30	7
	The reassessed tolerance for kumquat was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for kumquat consistent with orange.				

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Leeks	43350401 43383301	1.56	5	7	3
	The reassessed tolerance for leeks was based on residue data translated from green onions and is contingent upon label revisions to make the use pattern for leeks consistent with green onion.				
Lemon	43078701	6.25	3	30	7
	The reassessed tolerance for lemon was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for lemon consistent with orange.				
Lespedeza	43546101	1.25	2 per cutting	14	0
	The reassessed tolerances for lespedeza RACs were based on residue data translated from alfalfa and are contingent upon label revisions to make the use pattern for lespedeza consistent with alfalfa.				
Lettuce, head Lettuce, leaf	43362501 43367201	1.88	6	5	14
Lime	43078701	6.25	3	30	7
	The reassessed tolerance for lime was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for lime consistent with orange.				
Loganberry	44282201	2.0	4	7	1
	The reassessed tolerance for loganberry was based on residue data translated from blackberry and raspberry and is contingent upon label revisions to make the use pattern for loganberry consistent with blackberry and raspberry.				
Macadamia nut	44076801	0.94	7	7	1
Mango	44480301	1.25	8	7	1
Melon	43107602 44098401	1.0	6	7	1
Mint	44124801	0.94	3	7	7
Mushroom	44001101	1.7	4	3	1
Mustard greens	44271101	1.25	6	3	7
		2.50	3	7	7

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Nectarines	44120001	3.75	4	7	7
	The reassessed tolerance for nectarine was based on residue data translated from apricot and is contingent upon label revisions to make the use pattern for nectarine consistent with apricot.				
Oats	43350402 43414901	1.25	3	7	7
	The reassessed tolerances for oat RACs were based on residue data translated from wheat and are contingent upon label revisions to make the use pattern for oat consistent with wheat.				
Okra	44232701	1.5	6	7	1
Onions (bulb & green)	43350401 43383301	1.56	5	7	3
Orange	43078701	6.25	3	30	7
Papaya	44331001	1.25	13	3	1
Parsley	Additional data are required for the representative member celery, to reassess the existing crop group tolerance for leafy vegetables (except *Brassica* vegetables).				
Parsnip	44266401	1.25	5	7	7
	The reassessed tolerance for parsnip was based on residue data translated from turnip root and is contingent upon label revisions to make the use pattern for parsnip consistent with turnip.				
Passion fruit	44472801	1.25	8	7	3
Peach	44016001	3.75	5	11	7
Pear	44013701	1.25	5	7	1
Peas, dried	Only succulent type of peas are being supported for reregistration.				
Peas, succulent	44205901	2.5	5	7	3
Pecans	44383301	2.5	3	7	7
	The reassessed tolerance for pecan was based on residue data translated from walnut and is contingent upon label revisions to make the use pattern for pecan consistent with walnut.				
Peppers	43175501	1.56	5	5	3
Pineapple	44613801	5.0	3	7	7
Potatoes	43360401	1.56	2	7	0

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Pumpkin	43107602 44098401	1.0	6	7	1
	The reassessed tolerance for pumpkin was based on residue data translated from melon and is contingent upon label revisions to make the use pattern for pumpkin consistent with melon.				
Quince	The quince tolerance has not been reassessed. If adequate apple field trial data are submitted, they may be translated to quince contingent upon label revisions to make the use pattern for quince consistent with apple.				
Radish	44266401	1.25	5	7	7
	The reassessed tolerances for radish RACs were based on residue data translated from turnip RACs and are contingent upon label revisions to make the use pattern for radish consistent with turnip.				
Raspberry	44282201	2.0	4	7	1
Rice	43468101	1.25	3	7	7
Rutabaga	44266401	1.25	5	7	7
	The reassessed tolerance for rutabaga was based on residue data translated from turnip root and is contingent upon label revisions to make the use pattern for rutabaga consistent with turnip.				
Rye	43350402 43414901	1.25	3	7	7
	The reassessed tolerances for rye RACs were based on residue data translated from wheat and are contingent upon label revisions to make the use pattern for rye consistent with wheat.				
Salsify	44266401	1.25	5	7	7
	The reassessed tolerances for salsify RACs were based on residue data translated from turnip RACs and are contingent upon label revisions to make the use pattern for salsify consistent with turnip.				
Shallots	43350401 43383301	1.56	5	7	3
	The reassessed tolerance for shallots was based on residue data translated from green onions and is contingent upon label revisions to make the use pattern for shallots consistent with green onion.				
Sorghum	43360001	1.25	3	7	7
	Pending label revisions, adequate residue data are available to reassess the tolerance for sorghum grain. The available data on field corn aspirated grain fractions may be translated to sorghum aspirated grain fractions. Additional data are required for sorghum forage and stover.				
Spinach	44272401	2.0	3	7	7

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Squash (summer)	43370601	1.88	3	7	1
	The reassessed tolerance for summer squash was based on residue data translated from field-grown cucumber and is contingent upon label revisions to make the use pattern for summer squash consistent with cucumber.				
Squash (winter)	43107602 44098401	1.0	6	7	1
	The reassessed tolerance for winter squash was based on residue data translated from melon and is contingent upon label revisions to make the use pattern for winter squash consistent with melon.				
Strawberry	43368301 44094401	2.0	6	7	3
Sweet potatoes	43360401	1.56	2	7	0
	The reassessed tolerance for sweet potato was based on residue data translated from potato and is contingent upon label revisions to make the use pattern for sweet potato consistent with potato.				
Swiss chard	Additional data are required for the representative member celery, to reassess the existing crop group tolerance for leafy vegetables (except *Brassica* vegetables).				
Tangelo	43078701	6.25	3	30	7
	The available residue data for oranges may be translated to tangelos.				
Tangerines	43078701	6.25	3	30	7
	The reassessed tolerance for tangerine was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for tangerine consistent with orange.				
Tomato (incl. tomatillo)	43372901	3.43	5	5	3
		1.56	5	5	1
Turnip	44266401	1.25	5	7	7
Vetch	43545201 43546101	1.25	2 per cutting	14	0
	The reassessed tolerances for vetch RACs were based on residue data translated from alfalfa and clover and are contingent upon label revisions to make the use pattern for vetch consistent with alfalfa and clover.				
Walnuts	44383301	2.5	3	7	7
Watercress	44094801	1.25	5	3	3
Watermelon	43107602 44098401	1.0	6	7	1
Wheat (spring)	43350402 43414901	1.25	3	7	7
Wheat (winter)					

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Table 1 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Wild rice	43468101	1.25	3	7	7
	The reassessed tolerance for wild rice was based on residue data translated from rice and is contingent upon label revisions to make the use pattern for wild rice consistent with rice.				
Yams	43360401	1.56	2	7	0
	The available data for potatoes may be translated to yams.				

Table 2. Malathion Use Patterns from Field Trials in Support of Tolerances - ULV Formulations.

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Alfalfa	43546101	0.61	2 per cutting	14	0
Barley	43350402 43414901	0.61	3	7	7
	The reassessed tolerances for barley RACs were based on residue data translated from wheat and are contingent upon label revisions to make the use pattern for barley consistent with wheat.				
Beans, dry Beans, succulent	43372701 43376801 43417601	0.61	3	7	1
Cherries (sweet) Cherries (tart)	43078702 43108201	1.22	6	7	1
Clover	43545201	0.61	2	14	0
Corn, field	43468201 43577401	0.61	3	7	7
Corn, sweet	43361101	0.61	5	5	5
Cotton	43596601	1.22	25	3	0
	Adequate residue data are available to reassess the tolerance for cottonseed provided the registrant complies with the requested label revisions. A tolerance for cotton gin byproducts needs to be proposed following review of data which have been requested.				
Grapefruit	43078701	0.175	10	7	1
	The reassessed tolerance for grapefruit was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for grapefruit consistent with orange.				
Grasses (hay grass)	43362601	0.92	1	Not applicable	0
Kumquat	43078701	0.175	10	7	1
	The reassessed tolerance for kumquat was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for kumquat consistent with orange.				
Lemon	43078701	0.175	10	7	1
	The reassessed tolerance for lemon was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for lemon consistent with orange.				

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Table 2 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Lespedeza	43545201	0.61	2	14	0
	The reassessed tolerances for lespedeza RACs were based on residue data translated from alfalfa and are contingent upon label revisions to make the use pattern for lespedeza consistent with alfalfa.				
Lime	43078701	0.175	10	7	1
	The reassessed tolerance for lime was based on residue data translated from orange. Data translation is contingent upon label revisions to make the use pattern for lime consistent with orange.				
Lupine	43372701 43376801 43417601	0.61	3	7	1
	The reassessed tolerance for lupine seed was based on residue data translated from dry beans and is contingent upon label revisions to make the use pattern for lupine consistent with dry bean.				
Oats	43350402 43414901	0.61	3	7	7
	The reassessed tolerances for oat RACs were based on residue data translated from wheat and are contingent upon label revisions to make the use pattern for oat consistent with wheat.				
Orange	43078701	0.175	10	7	1
Rice	43468101	0.61	3	7	14
Rye	43350402 43414901	0.61	3	7	7
	The reassessed tolerances for rye RACs were based on residue data translated from wheat and are contingent upon label revisions to make the use pattern for rye consistent with wheat.				
Sorghum	43360001	0.61	3	7	7
	Pending label revisions, adequate residue data are available to reassess the tolerance for sorghum grain. The available data on field corn aspirated grain fractions may be translated to sorghum aspirated grain fractions. Additional data are required for sorghum forage and stover.				
Tangelo	43078701	0.175	10	7	1
	The available residue data for oranges may be translated to tangelos.				
Tangerine	43078701	0.175	10	7	1
	The reassessed tolerance for tangerine was based on residue data translated from orange and is contingent upon label revisions to make the use pattern for tangerine consistent with orange.				

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Table 2 (*continued*).

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Vetch	43545201	0.61	2	14	0
	The reassessed tolerances for vetch RACs were based on residue data translated from alfalfa and clover and are contingent upon label revisions to make the use pattern for vetch consistent with alfalfa and clover.				
Wheat, spring Wheat, winter	43350402 43414901	0.61	3	7	7
Wild rice	43468101	0.61	3	7	14
	The reassessed tolerance for wild rice was based on residue data translated from rice and is contingent upon label revisions to make the use pattern for wild rice consistent with rice.				

Table 3. Malathion Use Patterns in Support of Tolerances - Dust Formulations.

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i.)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Stored barley [a]	43661401	Loading: 0.624 lb ai/1,000 bushels Storage: 0.312 lb ai/1,000 bushels	3 per storage period	60	Not applicable
	The reassessed tolerance for barley grain was based on residue data translated from wheat grain and is contingent upon label revisions to make the use pattern for stored barley consistent with stored wheat.				
Stored corn [a]	43666801	Loading: 0.624 lb ai/1,000 bushels Storage: 0.312 lb ai/1,000 bushels	3 per storage period	60	Not applicable
Stored oats [a]	43661401	Loading: 0.624 lb ai/1,000 bushels Storage: 0.312 lb ai/1,000 bushels	3 per storage period	60	Not applicable
	The reassessed tolerance for oat grain was based on residue data translated from wheat grain and is contingent upon label revisions to make the use pattern for stored oats consistent with stored wheat.				
Stored rye [a]	43661401	Loading: 0.624 lb ai/1,000 bushels Storage: 0.312 lb ai/1,000 bushels	3 per storage period	60	Not applicable
	The reassessed tolerance for rye grain was based on residue data translated from wheat grain and is contingent upon label revisions to make the use pattern for stored rye consistent with stored wheat.				
Stored wheat [a]	43661401	Loading: 0.624 lb ai/1,000 bushels Storage: 0.312 lb ai/1,000 bushels	3 per storage period	60	Not applicable

[a] One application of 57EC formulation was made to the inside of the empty grain bin prior to treatment with the dust formulation.

Table 4. Malathion Use Patterns in Support of Tolerances - RTU Formulations.

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Cotton	43596601	1.22	25	3	0
	Adequate residue data are available to reassess the tolerance for cottonseed provided the registrant complies with the requested label revisions. A tolerance for cotton gin byproducts needs to be proposed following review of data which have been requested.				

Table 5. Malathion Use Patterns in Support of Tolerances - WP Formulations.

Supported Crop	MRID(s)	Maximum Single Application Rate (1b a.i./A)	Maximum Number of Applications Per Year	Minimum Application Interval (Days)	Minimum Pre-Harvest Interval (Days)
Blackberry	44282201	2.0	4	7	1
Boysenberry	44282201	2.0	4	7	1
	The reassessed tolerance for boysenberry was based on residue data translated from blackberry and raspberry and is contingent upon label revisions to make the use pattern for boysenberry consistent with blackberry and raspberry.				
Dewberry	44282201	2.0	4	7	1
	The reassessed tolerance for dewberry was based on residue data translated from blackberry and raspberry and is contingent upon label revisions to make the use pattern for dewberry consistent with blackberry and raspberry.				
Loganberry	44282201	2.0	4	7	1
	The reassessed tolerance for loganberry was based on residue data translated from blackberry and raspberry and is contingent upon label revisions to make the use pattern for loganberry consistent with blackberry and raspberry.				
Raspberry	44282201	2.0	4	7	1
Strawberry	43368301 44094401	2.0	6	7	3

cc: W. Smith (CEB-I).

7509C:CEB-I:WOS:wos:Rm805B:CM2:305-5353:08/16/00
RDI: FSuhre (08/16/00).